

REMARKS

Upon entry of this amendment, claims 1, 3, 6, and 8-28 are pending.

The undersigned would like to thank Examiner Andres for the telephone interview on March 17, 2004. The content of the interview is reflected in the amendment herein.

Rejections under 35 U.S.C. §112 second paragraph

The Examiner rejected claims 1, 3, 6, and 8-28 under 35 U.S.C. §112, second paragraph, as indefinite. Specifically, the Examiner alleges the terms “analog” and “variant” are ill defined. In the telephone interview on March 17, 2004, the Examiner conceded the claims are definite and agreed to withdraw the rejection. Therefore, Applicants respectfully request that this ground of rejection be withdrawn.

Rejections under 35 U.S.C. §103(a)

A. Rejection over WO 93/04692 (the “692 publication”) in view of
U.S. Patent No. 6,096,706 (Toback)

The Examiner rejected claims 1, 6, 12-15, 20, and 23-28 under 35 U.S.C. §103(a) as unpatentable over WO 93/04692 (the “692 publication”) in view of U.S. Patent No. 6,096,706 (Toback). Applicants respectfully traverse this ground of rejection for reasons below. Further, Applicants amended some of the claims to more clearly point out and distinctly claim the invention.

Applicants note that the primary reference, the ‘692 publication, describes an invention related to a method for protecting mammalian tissue from damages associated with the inflammatory response following a tissue injury (page 7, lines 10-14 of the ‘697 publication). The Summary of the Invention states that the invention of the ‘692 application provides “a method for alleviating the tissue destructive effects associated with the activation of the inflammatory response following tissue injury. The method comprises the step of providing to the affected tissue a therapeutically effective concentration of a morphogenic protein . . . sufficient to substantially inhibit or reduce the tissue destructive effects of the inflammatory response” (page 9, lines 3 to 12, emphasis added). Thus, the ‘692 publication teaches methods

to administer a morphogen to alleviate, inhibit, or prevent tissue destructive inflammation. The examples of the '692 publication teach subjecting tissues to morphogen before or after tissue injury, and to assess the tissue protecting effect of the morphogen (page 76, lines 1-3; page 77, lines 4-5; page 77, lines 23-25; page 78, lines 23-25).

In contrast, the pending claims of the present application relate to a method for evaluating the morphogenic activity of a morphogenic protein or its analog in terms of its ability to induce new tissue formation at a local defect site. Put in a different way, the claimed invention relates to evaluating the morphogenic activity of a morphogenic protein or its analog by determining whether such a compound can rebuild the injured tissue, not protect the tissue from injury, as described in the '692 application. The '692 application does not teach or suggest such aspect of the use of a morphogen. Therefore, Applicants submit that the '692 publication does not teach all elements of the instant claims. The secondary reference Toback does not provide what is missing from the primary reference. Toback describes novel polypeptides derived from Wound Growth Factor, which promote the growth of kidney epithelial cells in vitro and kidney repair after acute renal failure. In the background section, Toback enumerates OP-1 as one of the factors that is downregulated during acute renal failure (column 4, lines 6-14). Therefore, Toback teaches away from examining OP-1 or other morphogens for their ability to induce new tissue formation. Accordingly, the cited references, either alone or in combination, do not render obvious the claimed invention.

B. Rejection over WO 93/04692 (the "692 publication") in view of U.S. Patent No. 6,096,706 (Toback), further in view of Benet et al.

The Examiner rejected claims 3, 6, and 8-28 under 35 U.S.C. §103(a) as being unpatentable over the '692 application in view of Toback, further in view of Benet et al. As explained above, the primary reference, the '692 publication, describes an invention related to a method for protecting mammalian tissue from damages associated with the inflammatory response following a tissue injury (page 7, lines 10-14 of the '697 publication).

In contrast, the pending claims of the present application relate to a method for evaluating the optimal dosage of a morphogenic protein or its analog in terms of its ability to induce new tissue formation at a local defect site. As described above, the claimed invention

relates to evaluating the morphogenic activity of a morphogenic protein or its analog by determining whether such a compound can rebuild the injured tissue, not protect the tissue from injury, as described in the '692 application. The '692 application does not teach or suggest such aspect of the use of a morphogen. Therefore, Applicants submit that the '692 publication does not teach elements of the instant claims. The secondary reference Toback does not provide what is missing from the primary reference, and in fact teaches away from testing OP-1 or morphogens for tissue repair capacity. Accordingly, these claims are not obvious under these two cited references. The tertiary reference Benet describes dosage optimization, but does not provide any information regarding a morphogenic protein or its analog, let alone teach the use of morphogen to affect progenitor cells. Benet therefore does not provide what is missing from the primary and secondary references, making these rejected claims not obvious in view of these three combined references.

Therefore, Applicants respectfully request that the Examiner withdraw these reasons of rejection under 35 U.S.C. §103(a).

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Please charge our Deposit Account No. 18-1945, under Order No. JJJ-P01-570, for the requisite fee for a one-month extension from which the undersigned is authorized to draw. Applicant believes no additional fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 18-1945, under Order No. JJJ-P01-570 from which the undersigned is authorized to draw.

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